METHODS AND APPARATUS FOR A STENT HAVING AN EXPANDABLE WEB STRUCTURE

Reference to Related Applications

The present application is a continuation-in-part application of U.S. patent application Serial No. 09/582,318, filed June 23, 2000, which claims the benefit of the filing date of International Application PCT/EP99/06456, filed September 2, 1999, which claims priority from German application 19840645.2, filed September 5, 1998.

Field Of The Invention

The present invention relates to stents. More particularly, the present invention relates to stents having a web structure configured to expand from a contracted delivery configuration to an expanded deployed configuration.

Background Of The Invention

Various stent designs are known in the art. These stents form vascular prostheses fabricated from biocompatible materials. Stents are typically used to expand and maintain patency of hollow vessels, such as blood vessels or other body orifices. To this end, the

stent is often placed into a hollow vessel of a patient's body in a contracted delivery configuration and is subsequently expanded by suitable means, such as by a balloon catheter, to a deployed configuration.

A stent often comprises a stent body that is expandable from the contracted to the deployed configuration. A common drawback of such a stent is that the stent decreases in length, or foreshortens, along its longitudinal axis as it expands. Such shortening is undesirable because, in the deployed configuration, the stent may not span the entire area inside a vessel or orifice that requires expansion and/or support.

It therefore would be desirable to provide a stent that experiences reduced foreshortening during deployment.

It also would be desirable to provide a stent that is flexible, even in the contracted delivery configuration.

It would be desirable to provide a stent having radial stiffness in the expanded deployed configuration sufficient to maintain vessel patency in a stenosed vessel.

<u>Summary Of The Invention</u>

In view of the foregoing, it is an object of the present invention to provide a stent that experiences reduced foreshortening during deployment.

It is another object to provide a stent that is flexible, even in the contracted delivery configuration.

It is also an object to provide a stent having radial stiffness in the expanded deployed

configuration sufficient to maintain vessel patency in a stenosed vessel.

These and other objects of the present invention are accomplished by providing a stent having a tubular body whose wall has a web structure configured to expand from a contracted delivery configuration to an expanded deployed configuration. The web structure comprises a plurality of neighboring web patterns having adjoining webs. Each web has three sections: a central section arranged substantially parallel to the longitudinal axis in the contracted delivery configuration, and two lateral sections coupled to the ends of the central section. The angles between the lateral sections and the central section increase during expansion, thereby reducing or substantially eliminating length decrease of the stent due to expansion, while increasing a radial stiffness of the stent.

Preferably, each of the three sections of each web is substantially straight, the lateral sections preferably define obtuse angles with the central section, and the three sections are arranged relative to one another to form a concave or convex structure. When contracted to its delivery configuration, the webs resemble stacked or nested bowls or plates. This configuration provides a compact delivery profile, as the webs are packed against one another to form web patterns resembling rows of stacked plates.

Neighboring web patterns are preferably connected to one another by connection elements preferably formed as straight sections. In a preferred embodiment, the connection elements extend between adjacent web patterns from the points of

interconnection between neighboring webs within a given web pattern.

The orientation of connection elements between a pair of neighboring web patterns preferably is the same for all connection elements disposed between the pair. However, the orientation of connection elements alternates between neighboring pairs of neighboring web patterns. Thus, a stent illustratively flattened and viewed as a plane provides an alternating orientation of connection elements between the neighboring pairs: first upwards, then downwards, then upwards, etc.

As will be apparent to one of skill in the art, positioning, distribution density, and thickness of connection elements and adjoining webs may be varied to provide stents exhibiting characteristics tailored to specific applications. Applications may include, for example, use in the coronary or peripheral (e.g. renal) arteries. Positioning, density, and thickness may even vary along the length of an individual stent in order to vary flexibility and radial stiffness characteristics along the length of the stent.

Stents of the present invention preferably are flexible in the delivery configuration. Such flexibility beneficially increases a clinician's ability to guide the stent to a target site within a patient's vessel. Furthermore, stents of the present invention preferably exhibit high radial stiffness in the deployed configuration. Implanted stents therefore are capable of withstanding compressive forces applied by a vessel wall and maintain vessel patency. The web structure described hereinabove provides the desired combination of flexibility in the delivery configuration and radial stiffness in the deployed

configuration. The combination further may be achieved, for example, by providing a stent having increased wall thickness in a first portion of the stent and decreased wall thickness with fewer connection elements in an adjacent portion or portions of the stent.

Depending on the material of fabrication, a stent of the present invention may be either self-expanding or expandable by other suitable means, for example, using a balloon catheter. Self-expanding embodiments preferably are fabricated from a superelastic material, such as a nickel-titanium alloy. Regardless of the expansion mechanism used, the beneficial aspects of the present invention are maintained: reduced shortening upon expansion, high radial stiffness, and a high degree of flexibility.

Methods of using stents in accordance with the present invention are also provided.

Brief Description Of The Drawings

The above and other objects and advantages of the present invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference numerals refer to like parts throughout, and in which:

FIG. 1 is a schematic isometric view illustrating the basic structure of a stent according to the present invention;

FIG. 2 is a schematic view illustrating a web structure of a wall of the stent of FIG. 1 in a contracted delivery configuration;

FIG. 3 is a schematic view illustrating the web structure of the stent of FIG. 1 in an expanded deployed configuration;

FIG. 4 is an enlarged schematic view of the web structure in the delivery configuration;

FIG. 5 is a schematic view of an alternative web structure of the stent of FIG. 1 having transition sections and shown in an as-manufactured configuration;

FIGS. 6A and 6B are, respectively, a schematic view and detailed view of an alternative embodiment of the web structure of FIG. 5;

FIGS. 7A-7D are, respectively, schematic and detailed views of another alternative embodiment of the web structure of the stent of the present invention, and a cross-sectional view of the stent;

FIGS. 8A and 8B are views further alternative embodiments of the stent of the present application having different interconnection patterns;

FIGS. 9A and 9B are, respectively, a schematic and detailed view of yet another alternative embodiment of the web structure of FIG. 5; and

FIGS. 10A-10D illustrate a method of deploying a balloon expandable embodiment of a stent constructed in accordance with the present invention.

Detailed Description Of The Invention

Referring to FIG. 1, stent 1 comprises tubular flexible body 2. Tubular flexible body 2, in turn, comprises wall 3 having a web structure, as described hereinbelow with respect to FIGS. 2-9. Stent 1 and its web structure are expandable from a contracted delivery configuration to an expanded deployed configuration. Depending on the material of fabrication, stent 1 may be either self-expanding or

expandable using a balloon catheter. If self-expanding, the web structure is preferably fabricated from a superelastic material, such as a nickel-titanium alloy. Furthermore, stent 1 preferably is fabricated from biocompatible or biodegradable materials. It also may be radiopaque to facilitate delivery, and it may comprise an external coating **C** that retards thrombus formation or restenosis within a vessel. The coating alternatively may deliver therapeutic agents into the patient's blood stream.

With reference to FIGS. 2-4, a first embodiment of the web structure of stent 1 is described. In FIGS. 2-4, wall 3 of body 2 of stent 1 is shown flattened into a plane for illustrative purposes. FIG. 2 shows web structure 4 in a contracted delivery configuration, with line **L** indicating the longitudinal axis of the stent. Web structure 4 comprises neighboring web patterns 5 and 6 arranged in alternating, side-by-side fashion. Thus, the web patterns seen in FIG. 2 are arranged in the sequence 5, 6, 5, 6, 5, etc.

FIG. 2 illustrates that web patterns 5 comprise adjoining webs 9 (concave up in FIG. 2), while web patterns 6 comprise adjoining webs 10 (convex up in FIG. 2). Each of these webs has a concave or convex shape resulting in a stacked plate- or bowl-like appearance when the stent is contracted to its delivery configuration. Webs 9 of web patterns 5 are rotated 180 degrees with respect to webs 10 of web patterns 6, i.e., alternating concave and convex shapes. The structure of webs 9 and 10 is described in greater detail hereinbelow with respect to FIG. 4.

Neighboring web patterns 5 and 6 are interconnected by connection elements 7 and 8. A plurality of connection elements 7 and 8 are provided longitudinally between each pair of web patterns 5 and 6. Multiple connection elements 7 and 8 are disposed in the circumferential direction between adjacent webs 5 and 6. The position, distribution density, and thickness of these pluralities of connection elements may be varied to suit specific applications in accordance with the present invention.

Connection elements 7 and 8 exhibit opposing orientation. However, all connection elements 7 have the same orientation that, as seen in FIG. 2, extends from the left side, bottom, to the right side, top. Likewise, all connection elements 8 have the same orientation that extends from the left side, top, to the right side, bottom. Connection elements 7 and 8 alternate between web patterns 5 and 6, as depicted in FIG. 2.

FIG. 3 illustrates the expanded deployed configuration of stent 1, again with reference to a portion of web structure 4. When stent 1 is in the expanded deployed configuration, web structure 4 provides stent 1 with high radial stiffness. This stiffness enables stent 1 to remain in the expanded configuration while, for example, under radial stress. Stent 1 may experience application of radial stress when, for example, implanted into a hollow vessel in the area of a stenosis.

FIG. 4 is an enlarged view of web structure 4 detailing a portion of the web structure disposed in the contracted delivery configuration of FIG. 2. FIG. 4 illustrates that each of webs 9 of web pattern 5 comprises three sections 9a, 9b and 9c, and each of

webs 10 of web pattern 6 comprises three sections 10a, 10b and 10c. Preferably, each individual section 9a, 9b, 9c, 10a, 10b and 10c, has a straight configuration.

Each web 9 has a central section 9b connected to lateral sections 9a and 9c, thus forming the previously mentioned bowl- or plate-like configuration. Sections 9a and 9b enclose obtuse angle α. Likewise, central section 9b and lateral section 9c enclose obtuse angle β. Sections 10a-10c of each web 10 of each web pattern 6 are similarly configured, but are rotated 180 degrees with respect to corresponding webs 9. Where two sections 9a or 9c, or 10a or 10c adjoin one another, third angle γ is formed (this angle is zero where the stent is in the fully contracted position, as shown in FIG. 4).

Preferably, central sections 9b and 10b are substantially aligned with the longitudinal axis **L** of the tubular stent when the stent is in the contracted delivery configuration. The angles between the sections of each web increase in magnitude during expansion to the deployed configuration, except that angle γ, which is initially zero or acute, approaches a right angle after deployment of the stent. This increase provides high radial stiffness with reduced shortening of the stent length during deployment. As will of course be understood by one of ordinary skill, the number of adjoining webs that span a circumference of the stent preferably is selected corresponding to the vessel diameter in which the stent is intended to be implanted.

FIG. 4 illustrates that, with stent 1 disposed in the contracted delivery configuration, webs 9 adjoin each other in an alternating fashion and are

each arranged like plates stacked into one another, as are adjoining webs 10. FIG. 4 further illustrates that the configuration of the sections of each web applies to all of the webs which jointly form web structure 4 of wall 3 of tubular body 2 of stent 1. Webs 9 are interconnected within each web pattern 5 via rounded connection sections 12, of which one connection section 12 is representatively labeled. Webs 10 of each neighboring web pattern 6 are similarly configured.

FIG. 4 also once again demonstrates the arrangement of connection elements 7 and 8. Connection elements 7, between a web pattern 5 and a neighboring web pattern 6, are disposed obliquely relative to the longitudinal axis **L** of the stent with an orientation **A**, which is the same for all connection elements 7. Orientation **A** is illustrated by a straight line that generally extends from the left side, bottom, to the right side, top of FIG. 4. Likewise, the orientation of all connection elements 8 is illustrated by line **B** that generally extends from the left side, top, to the right side, bottom of FIG. 4. Thus, an alternating **A**, **B**, **A**, **B**, etc., orientation is obtained over the entirety of web structure 4 for connection elements between neighboring web patterns.

Connection elements 7 and 8 are each configured as a straight section that passes into a connection section 11 of web pattern 5 and into a connection section 11' of web pattern 6. This is illustratively shown in FIG. 4 with a connection element 7 extending between neighboring connection sections 11 and 11', respectively. It should be understood that this represents a general case for all connection elements 7 and 8.

Since each web consists of three interconnected sections that form angles α and β with respect to one another, which angles are preferably obtuse in the delivery configuration; expansion to the deployed configuration of FIG. 3 increases the magnitude of angles α and β. This angular increase beneficially provides increased radial stiffness in the expanded configuration. Thus, stent 1 may be flexible in the contracted delivery configuration to facilitate delivery through tortuous anatomy, and also may exhibit sufficient radial stiffness in the expanded configuration to ensure vessel patency, even when deployed in an area of stenosis. The increase in angular magnitude also reduces and may even substantially eliminate length decrease of the stent due to expansion, thereby decreasing a likelihood that stent 1 will not completely span a target site within a patient's vessel post-deployment.

The stent of FIG. 4 is particularly well-suited for use as a self-expanding stent when manufactured, for example, from a shape memory alloy such as nickel-titanium. In this case, web patterns 5 and 6 preferably are formed by laser-cutting a tubular member, wherein adjacent webs 9 and 10 are formed using slit-type cuts. Only the areas circumferentially located between connection members 7 and 8 (shaded area **D** in FIG. 4) require removal of areas of the tubular member. These areas also may be removed from the tubular member using laser cutting techniques.

Referring now to FIG. 5, an alternative embodiment of the web structure of stent 1 is described. FIG. 5 shows the alternative web structure in an as-manufactured configuration. The basic pattern of the embodiment of FIG. 5 corresponds to that of the

embodiment of FIGS. 2-4. Thus, this alternative embodiment also relates to a stent having a tubular flexible body with a wall having a web structure configured to expand from a contracted delivery configuration to the deployed configuration.

Likewise, the web structure again comprises a plurality of neighboring web patterns, of which two are illustratively labeled in FIG. 5 as web patterns 5 and 6. Web patterns 5 and 6 are again provided with adjoining webs 9 and 10, respectively. Each of webs 9 and 10 is subdivided into three sections, and reference is made to the discussion provided hereinabove, particularly with respect to FIG. 4. As will of course be understood by one of skill in the art, the stent of FIG. 5 will have a smaller diameter when contracted (or crimped) for delivery, and may have a larger diameter than illustrated in FIG. 5 when deployed (or expanded) in a vessel.

The embodiment of FIG. 5 differs from the previous embodiment by the absence of connection elements between web patterns. In FIG. 5, web patterns are interconnected to neighboring web patterns by transition sections 13, as shown by integral transition section 13 disposed between sections 9c and 10c. Symmetric, inverted web patterns are thereby obtained in the region of transition sections 13. To enhance stiffness, transition sections 13 preferably have a width greater than twice the width of webs 9 or 10.

As seen in FIG. 5, every third neighboring pair of webs 9 and 10 is joined by an integral transition section 13. As will be clear to those of skill in the art, the size and spacing of transition sections 13 may be altered in accordance with the principles of the present invention.

An advantage of the web structure of FIG. 5 is that it provides stent 1 with compact construction coupled with a high degree of flexibility in the delivery configuration and high load-bearing capabilities in the deployed configuration. Furthermore, FIG. 5 illustrates that, as with connection elements 7 and 8 of FIG. 4, transition sections 13 have an alternating orientation and are disposed obliquely relative to the longitudinal axis of the stent (shown by reference line **L**). FIG. 5 also illustrates that, especially in the deployed configuration, an H-like configuration of transition sections 13 with adjoining web sections is obtained.

The stent of FIG. 5 is well-suited for use as a balloon-expandable stent, and may be manufactured from stainless steel alloys. Unlike the stent of FIG. 4, which is formed in the contracted delivery configuration, the stent of FIG. 5 preferably is formed in a partially deployed configuration by removing the shaded areas **D'** between webs 9 and 10 using laser-cutting or chemical etching techniques. In this case, central sections 9b and 10b are substantially aligned with the longitudinal axis **L** of the stent when the stent is crimped onto the dilatation balloon of a delivery system.

Referring now to FIGS. 6 and 7, alternative embodiments of the web structure of FIG. 5 are described. These web structures differ from the embodiment of FIG. 5 in the spacing of the transition sections. Web structure 15 of FIGS. 6A and 6B provides a spacing of transition sections 16 suited for use in the coronary arteries. FIG. 6A shows the overall arrangement, while FIG. 6B provides a detail view of region A of FIG. 6A. Other arrangements and spacings

will be apparent to those of skill in the art and fall within the scope of the present invention.

Web structure 17 of FIGS. 7A-7D provides stent 1 with a variable wall thickness and a distribution density or spacing of transition sections 16 suited for use in the renal arteries. FIG. 7A shows the arrangement of web structure 17 along the length of stent 1, and demonstrates the spacing of transition sections 18. FIGS. 7C and 7D provide detail views of regions A and B, respectively, of FIG. 7A, showing how the spacing and shape of the webs that make up web structure 17 change as stent 1 changes along its length. In particular, as depicted (not to scale) in FIG. 7D, stent 1 has first thickness $\mathbf{t_1}$ for first length $\mathbf{L_1}$ and second thickness $\mathbf{t_2}$ for second length $\mathbf{L_2}$.

The variation in thickness, rigidity and number of struts of the web along the length of the stent of FIGS. 7A-7D facilitates use of the stent in the renal arteries. For example, the thicker region $\mathbf{L_1}$ includes more closely spaced and sturdier struts to provide a high degree of support in the ostial region, while the thinner region $\mathbf{L_2}$ includes fewer and thinner struts to provide greater flexibility to enter the renal arteries. For such intended applications, region $\mathbf{L_1}$ preferably has a length of about 6-8 mm and a nominal thickness $\mathbf{t_1}$ of 0.21 mm, and region $\mathbf{L_2}$ has a length of about 5 mm and a nominal thickness $\mathbf{t_2}$ of about 0.15 mm.

As depicted in FIGS. 7A-7D, the reduction in wall thickness may occur as a step along the exterior of the stent, such as may be obtained by grinding or chemical etching. One of ordinary skill in the art will appreciate, however, that the variation in thickness may occur gradually along the length of the

stent, and that the reduction in wall thickness could be achieved by alternatively removing material from the interior surface of the stent, or both the exterior and interior surfaces of the stent.

In FIGS. 8A and 8B, additional embodiments of web structures of the present invention, similar to FIG. 5, are described, in which line **L** indicates the direction of the longitudinal axis of the stent. In FIG. 5, every third neighboring pair of webs is joined by an integral transition section 13, and no set of struts 9a-9c or 10a-10c directly joins two transition sections 13. In the embodiment of FIG. 8A, however, integral transition sections 20 are arranged in a pattern so that the transition sections span either four or three adjacent webs. For example, the portion indicated as 22 in FIG. 8A includes three consecutively joined transition sections, spanning four webs. In the circumferential direction, portion 22 alternates with the portion indicated at 24, which includes two consecutive transition sections, spanning three webs.

By comparison, the web pattern depicted in FIG. 8B includes only portions 24 that repeat around the circumference of the stent, and span only three webs at a time. As will be apparent to one of ordinary skill, other arrangements of integral transition regions 13 may be employed, and may be selected on an empirical basis to provide any desired degree of flexibility and trackability in the contracted delivery configuration, and suitable radial strength in the deployed configuration.

Referring now to FIGS. 9A and 9B, a further alternative embodiment of the stent of FIG. 8B is described, in which the transition sections are formed with reduced thickness. Web structure 26 comprises

transition sections 27 disposed between neighboring web patterns. Sections 27 are thinner and comprise less material than transition sections 20 of the embodiment of FIG. 8B, thereby enhancing flexibility without significant reduction in radial stiffness.

Referring now to FIGS. 10A-10D, a method of using a balloon expandable embodiment of stent 1 is provided. Stent 1 is disposed in a contracted delivery configuration over balloon 30 of balloon catheter 32. As seen in FIG. 10A, the distal end of catheter 32 is delivered to a target site **T** within a patient's vessel **V** using, for example, well-known percutaneous techniques. Stent 1 or portions of catheter 32 may be radiopaque to facilitate positioning within the vessel. Target site **T** may, for example, comprise a stenosed region of vessel **V** at which an angioplasty procedure has been conducted.

In FIG. 10B, balloon 30 is inflated to expand stent 1 to the deployed configuration in which it contacts the wall of vessel **V** at target site **T**. Notably, the web pattern of stent 1 described hereinabove minimizes a length decrease of stent 1 during expansion, thereby ensuring that stent 1 covers all of target site **T**. Balloon 30 is then deflated, as seen in FIG. 10C, and balloon catheter 32 is removed from vessel **V**, as seen in FIG. 10D.

Stent 1 is left in place within the vessel. Its web structure provides radial stiffness that maintains stent 1 in the expanded configuration and minimizes restenosis. Stent 1 may also comprise external coating **C** configured to retard restenosis or thrombosis formation around the stent. Coating **C** may

alternatively deliver therapeutic agents into the patient's blood stream.

Although preferred illustrative embodiments of the present invention are described hereinabove, it will be evident to one skilled in the art that various changes and modifications may be made therein without departing from the invention. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.